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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,152	03/01/2004	Robert P. van Weeghel	2183-6372US	3166

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EXAMINER	
GABEL, GAILENE	
ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,152	VAN WEEGHEL ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11,12 and 17-20* is/are pending in the application.

4a) Of the above claim(s) *1,11 and 18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,11,12 and 17-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/4/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed on June 4, 2007, is acknowledged and has been entered. Claims 2-10 and 13-16 have been cancelled. Claims 12 and 17 have been amended. Claims 1, 11 and 18-20 have been amended and remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 1, 11, 12, and 17-20 are pending. Claims 12 and 17 are under examination.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Withdrawn Rejections/Objections

3. All rejections or objections not reiterated herein, have been withdrawn.

4. The rejections of claims 13-16 are now moot in light of Applicant's cancellation of the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 12 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite and unclear in reciting, "a first marker antibody with hemoglobin F." Perhaps, Applicant intends, "a first antibody reactive with hemoglobin F," instead.

Claim 17 is indefinite and unclear in reciting, "reactive with carbonic anhydrase B a red blood cell." Perhaps, Applicant intends, "reactive with carbonic anhydrase B of a red blood cell," instead.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taniguchi et al. (Carbonic anhydrase isozymes, hemoglobin-F and glutathione levels in lead-exposed workers, Clinica Chimica Acta: International Journal of Clinical Chemistry, (1975 Feb 22) Vol. 59, No. 1, pp. 29-34) *in light of Funakoshi et al. (Human Carbonic Anhydrases, the Journal of Biological Chemistry 245 (11): 2852-2856 (1970))* and *Tamachi (Immunological Determination of Human Fetal Hemoglobin, Z. Klin. Chem. Klin. Biochem. 11: 501-505 (1973))*, and in view of Golbus (US Patent 5,962,234).

Taniguchi et al. teach using single radial immunodiffusion technique in determining levels of carbonic anhydrase B and hemoglobin F (Hgb F) in order to study the effect of lead in red cell components (see Summary and Introduction). Taniguchi et al. specifically teach using reagents reactive with hemoglobin F (Hgb F) present in red blood cells and reagents reactive with carbonic anhydrase B present in red blood cells (see page 30: Immunological technique and page 31: Table 1). According to Taniguchi, the reagent and method used to assay carbonic anhydrase B is described in Funakoshi et al. and the reagent and method used to assay Hgb F is described in Tamachi.

Funakoshi et al. teach that the reagent used to assay carbonic anhydrase B is antibody that is reactive to carbonic anhydrase B (see page 2853 columns 1 and 2 of

Funakoshi et al.). Tamachi teaches that the reagent used to assay Hgb F is antibody that is reactive to Hgb F (see page 502 columns 1 and 2 of Tamachi).

As such, Taniguchi et al. specifically teach using reagents comprising a first antibody reactive with Hgb F present in red blood cells and a second antibody reactive with carbonic anhydrase B present in red blood cells.

Taniguchi et al. differ from the instant invention in failing to teach that reagents comprising antibody reactive with carbonic anhydrase and antibody reactive with Hgb F are detectably labeled using flow cytometry. Taniguchi et al. also does not teach a kit.

Golbus discloses a kit and reagent system for identifying and differentiating subsets of erythrocytes including fetal nucleated erythrocyte. The reagent system and kit comprises any combination of a labeled nucleic acid probe reactive with DNA of a red blood cell, a labeled anti-embryonic hemoglobin antibody or anti-Hgb E reactive with embryonic hemoglobin or Hgb E, and labeled anti-Hgb F antibody reactive with Hgb F component of the red blood cell. See column 15, lines 7-38. Golbus discloses incorporating the reagents into a kit format used in flow cytometric assays (see column 15, lines 46-54).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the reagent mixture of Taniguchi, into a kit format containing individually detectable labels, as taught by Golbus, because Golbus specifically taught conjugating labels into antibodies for purposes of detecting bound components, the practice of which is conventional and well-known in the art. One of ordinary skill in the art at the time of the instant invention would have been motivated to

incorporate the reagents as taught by Taniguchi into a kit format as taught by Golbus, because kits are conventional and well-known in the art for their recognized advantage of convenience and economy.

Response to Arguments

7. Applicant's arguments with respect to claims 12 and 17 have been considered but are moot in view of the new grounds of rejection.

8. No claims are allowed.

9. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel
Primary Examiner
Art Unit 1641

August 15, 2007